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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,969	09/11/2003	Wael R. Joseph	19378B (27839-725)	5031
45736 7590 06/16/2009 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102				
EXAMINER AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
06/16/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

### Office Action Summary

**Application No.**

10/659,969

**Applicant(s)**

JOSEPH ET AL.

**Examiner**

HASAN S. AHMED

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10, 12-33, 35-40, 42 and 44-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-33, 35-40, 42 and 44-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

- Receipt is acknowledged of applicants' amendment, remarks, and RCE, all filed on 30 March 2009.
- Applicants' remarks of 30 March 2009 have been considered but are moot in view of the new grounds of rejection.

\* \* \* \* \*

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 30 March 2009 has been entered.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-8, 10, 12-22, 25-30, 32, 33, 35-40, 42, 44-55, 58-60, 62-66, 68 and 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 ("Krzysik") (cited in the IDS of 18 October 2004).

Krzysik teaches an absorbent product (*see* page 3, line 78). The absorbent product disclosed is comprised of:

- the moisturizing and lubricating compositions of instant claims 1, 32, and 62 (*see* page 3, lines 93-103);
- the emollient (dimethicone) of instant claims 1 and 62 (*see* page 19, formula 6);
- the humectant (glycerin) of instant claims 1, 32, and 62 (*see* page 5, line 150);
- the immobilizing agent (PEG 8000) of instant claims 1, 32, and 62 (*see* page 5, line 156);
- the compatibilizing agent (propylene glycol) of instant claims 1, 32, and 62 (*see* page 5, lines 149-150);
- the silicone (dimethicone) of instant claim 2 (*see* page 19, formula 6);
- the dimethicone of instant claims 3 and 35 (*see* page 19, formula 6);
- the glycerin of instant claims 5-7 and 37-39 (*see* page 5, line 150);
- the PEG 8000 of instant claims 1, 10, 42, and 62 (*see* page 5, line 156);
- the propylene glycol of instant claims 12 and 44 (*see* page 5, lines 149-150);
- the dispersing agent (DC 1428) of instant claims 13 and 63 (*see* page 19, formula 6);
- the modified polydimethylsiloxane (DC 1428) of instant claim 14 (*see* page 19, formula 6);
- the skin barrier enhancing agent (natural fats or oils) of instant claims 16, 46, and 64 (*see* page 3, line 100);
- the avocado oil of instant claims 17 and 47 (*see* page 7, line 215);

- the antioxidant (tocopherol) of instant claims 18 and 65 (*see* page 18, formula 1);
- the tocopherol of instant claims 19, 20, 49, and 50 (*see* page 18, formula 1);
- the sterol derivative of instant claims 21 and 66 (*see* page 3, line 99);
- the cholesterol of instant claims 21, 22, 51, and 52 (*see* page 5, line 160);
- the surfactant of instant claims 25, 53, and 68 (*see* page 3, line 98); and
- the sorbitol of instant claim 70 (*see* page 5, line 158).

Krzysik explains that the disclosed absorbent product is beneficial because it improves skin health by enhancement of skin barrier function (*see* page 1, lines 7-8).

Krzysik does not explicitly teach all the percentages recited in instant claims 1, 4, 8, 15, 18, 21, 26, 27, 32, 36, 40, 45, 48, 51, 54, 55, and 71-74 (or the ratio recited in instant claim 33), however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges. The Krzysik reference teaches ranges that overlap with the instant claims regarding: (a) emollient (10% - *see* page 19, formula 6); (b) humectant (hydrophilic solvent, i.e.,

glycerin (see page 5, line 150)) (10-95% - see page 3, line 94); (c) immobilizing agent (high MW PEG) (5-95% - see page 3, lines 94-95); (d) compatibilizing agent (hydrophilic solvent, i.e., propylene glycol (see page 5, lines 149-150)) (10-95% - see page 3, line 94); (e) skin barrier enhancing agent (natural fats or oils) (0.1 - 30% - see page 3, line 100); (f) antioxidant (tocopherol) (0.3% - see page 18, formula 1); (g) melting point (30 degrees C - 100 degrees C – page 5, line 141); and (h) penetration hardness (5 millimeters - 360 millimeters – page 5, line 142-143).

The Krzysik reference is silent with respect to the (1) phase temperatures of instant claims 1, 28-30, 32, 58-60, and 62; and (2) solubility/dispersibility in deionized water of instant claims 1, 32, 62, and 70. As claimed, applicants' article is the same as the prior art. As claimed, it contains the same components in the same configuration and overlapping amounts. Properties are the same when the structure and composition are the same. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product, as taught by Krzysik. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they improve skin health by enhancement of skin barrier function, as explained by Krzysik (see above)

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2. Claims 1, 23, 24, 32, 56, 57, 62, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 ("Krzysik") in view of US 5,342,976 ("Bowser").

Krzysik teaches an absorbent product (*see above*).

The Krzysik reference differs from the instant application in that it does not teach the ceramide of claims 23, 56, and 67 or the glucosylceramide of instant claims 24 and 57.

Bowser teaches a skin composition that may be used in an absorbent product, such as a tissue wipe (*see col. 16, line 44*).

The disclosed composition contains the ceramide glucosylceramide (*see col. 1, line 67*).

Bowser explains that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." *See col. 2, lines 7-9.*

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add glucosylceramide to an absorbent product, as taught by Krzysik in view of Bowser. One of ordinary skill in the art at the time the invention was made would have been motivated to this ingredient into a tissue product for the beneficial effect of enhancing skin barrier function, as explained by Bowser.

\*

3. Claims 1, 31, 61, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 ("Krzysik") in view of US 6,153,209 ("Vega").

Krzysik is discussed above. Krzysik differs from the instant application in that it does not teach the particular absorbent products listed in claims 31, 61, and 69.

Vega teaches an absorbent product (see col. 1, line 7) comprising a moisturizing and lubricating composition (see col. 25, line 65 - col. 26, line 14) which in turn is comprised of an emollient (see col. 15, line 26), a humectant (see col. 25, line 65 - col. 26, line 14), an immobilizing agent (e.g. PEG-30 and PEG-50, see col. 26, line 6), and a compatibilizing agent (e.g. propylene glycol, see col. 26, lines 5-11). The absorbent product disclosed by Vega is, *inter alia*, a diaper (see col. 1, line 7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product such as a diaper, as taught by Krzysik in view of Vega. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they improve skin health by enhancement of skin barrier function, as explained by Krzysik (see above)

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.



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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 12-33, 35-40, 42, and 44-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862 ('862). Although the conflicting claims are not identical, they are not patentably distinct from each other because '862 claims a tissue product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. *See* claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615